General

Guideline Title

2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.

Bibliographic Source(s)

Goff DC Jr, Lloyd-Jones DM, Bennett G, Coady S, D'Agostino RB Sr, Gibbons R, Greenland P, Lackland DT, Levy D, O'Donnell CJ, Robinson JG, Schwartz JS, Shero ST, Smith SC Jr, Sorlie P, Stone NJ, Wilson PW. 2013 ACC/AHA guideline on the assessment ofÂ cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2935-59. [66 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): National Heart, Lung and Blood Institute (NHLBI) Evidence Statements are included for each recommendation. See Appendices 4 and 5 in the original guideline document.

Each recommendation has been mapped from the NHLBI grading format to the American College of Cardiology/American Heart Association Class of Recommendation/Level of Evidence (ACC/AHA COR/LOE) construct and is expressed in both formats. Because of the inherent differences in grading systems and the clinical questions driving the recommendations, alignment between the NHLBI and ACC/AHA formats is in some cases imperfect. Definitions for the NHLBI strength of recommendation (A-E, N) and quality of evidence (High, Moderate, Low) and the ACC/AHA levels of the evidence (LOE: A-C) and classes of recommendations (COR: I-III) are provided at the end of the "Major Recommendations" field.

Summary of Recommendations for Risk Assessment

Assessment of 10-Year Risk of a First Hard Atherosclerotic Cardiovascular Disease (ASCVD) Event

1. The race- and sex-specific Pooled Cohort Equations* to predict 10-year risk of a first hard ASCVD event should be used in non-Hispanic African Americans and non-Hispanic whites, 40–79 years of age. NHLBI Grade: B (Moderate); ACC/AHA COR: I; ACC/AHA LOE: B (Dawber, Kannel, & Lyell, 1963; Fried et al., 1991; Kannel et al., 1979; "The Atherosclerosis Risk in Communities (ARIC) Study," 1989)
2. Use of the sex-specific Pooled Cohort Equations for non-Hispanic whites may be considered for estimation of risk in patients from

populations other than African Americans and non-Hispanic whites. NHLBI Grade: E (Expert Opinion); ACC/AHA COR: IIb; ACC/AHA LOE: C

Critical Question (CQ) 1: Use of Newer Risk Markers after Quantitative Risk Assessment

1. If, after quantitative risk assessment, a risk-based treatment decision is uncertain, assessment of ≥1 of the following–family history, high-sensitivity C-reactive protein (hs-CRP), coronary artery calcium (CAC) score, or ankle-brachial index (ABI)–may be considered to inform treatment decision making. NHLBI Grade: E (Expert Opinion); ACC/AHA COR: IIb†; ACC/AHA LOE: B (Buckley et al., 2009; Empana et al., 2011; Ankle Brachial Index Collaboration et al., 2008; Helfand et al., 2009; Emerging Risk Factors Collaboration et al., 2010; Kashani et al., 2013; U.S. Preventive Services Task Force (USPSTF), 2013; Peters et al., 2012; Schnell-Inderst et al., 2010)
2. Routine measurement of carotid intima-media thickness (CIMT) is not recommended in clinical practice for risk assessment for a first ASCVD event. NHLBI Grade: N (No recommendation for or against); ACC/AHA COR: III: No Benefit†; ACC/AHA LOE: B (Helfand et al., 2009; Peters et al., 2012; Den Ruijter et al., 2012)
3. The contribution of apolipoprotein B (ApoB), chronic kidney disease (CKD), albuminuria, and cardiorespiratory fitness to risk assessment for a first ASCVD event is uncertain at present. NHLBI Grade: N (No recommendation for or against)

CQ2: Long-Term Risk Assessment

1. It is reasonable to assess traditional ASCVD risk factors‡ every 4 to 6 years in adults 20 to 79 years of age who are free from ASCVD and to estimate 10-year ASCVD risk every 4 to 6 years in adults 40 to 79 years of age who are free from ASCVD. NHLBI Grade: B (Moderate); ACC/AHA COR: IIa; ACC/AHA LOE: B (Karp et al., 2004; Pencina et al., 2009)
2. Assessment of 30-year or lifetime ASCVD risk on the basis of traditional risk factors‡ may be considered in adults 20 to 59 years of age who are free from ASCVD and are not at high short-term risk. NHLBI Grade: C (Weak); ACC/AHA COR: IIb; ACC/AHA LOE: C (Pencina et al., 2009; Lloyd-Jones et al., 2006; Lloyd-Jones et al., 2004)

A downloadable spreadsheet enabling estimation of 10-year and lifetime risk of ASCVD and a Web-based calculator is available from the American Heart Association Web site and the American College of Cardiology Web site.

*Derived from the ARIC (Atherosclerosis Risk in Communities) study (1989), Cardiovascular Health Study (Fried et al., 1991), CARDIA (Coronary Artery Risk Development in Young Adults) study (Friedman et al., 1988), and Framingham original and offspring cohorts (Dawber, Kannel, & Lyell, 1963; Kannel et al., 1979).

†Based on new evidence reviewed during ACC/AHA update of evidence.

‡Age, sex, total cholesterol, high-density lipoprotein cholesterol, systolic BP, use of antihypertensive therapy, diabetes, and current smoking.

Definitions:

NHLBI Grading of the Strength of Recommendations

Note: Each recommendation has been mapped from the National Heart, Lung and Blood Institute (NHLBI) grading format below to the American College of Cardiology/American Heart Association (ACC/AHA) Classification of Recommendation/Level of Evidence (COR/LOE) construct (see the "Rating Scheme for the Strength of the Evidence" field) and is expressed in both formats.

NHLBI Grading of the Strength of Recommendations

Grade	Strength of Recommendation*
A	Strong recommendation There is high certainty based on evidence that the net benefit† is substantial.
B	Moderate recommendation There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.
C	Weak recommendation There is at least moderate certainty based on evidence that there is a small net benefit.
D	Recommendation against There is at least moderate certainty based on evidence that there is no net benefit or that risks/harms outweigh benefits.

Grade	Strength of Recommendation*
E	Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group recommends.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the Work Group thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area.
N	No recommendation for or against ("There is insufficient evidence or evidence is unclear or conflicting.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Work Group thought no recommendation should be made. Further research is recommended in this area.

*In most cases, the strength of the recommendation should be closely aligned with the quality of the evidence; however, under some circumstances, there may be valid reasons for making recommendations that are not closely aligned with the quality of the evidence (e.g., strong recommendation when the evidence quality is moderate, such as smoking cessation to reduce cardiovascular disease [CVD] risk or ordering an electrocardiogram [ECG] as part of the initial diagnostic work-up for a patient presenting with possible myocardial infarction [MI]). Those situations should be limited and the rationale explained clearly by the Work Group.

†Net benefit is defined as benefits minus risks/harms of the service/intervention.

NHLBI Quality Rating of the Strength of Evidence

Type of Evidence	Quality Rating*
• Well-designed, well-executed† randomized controlled trials (RCTs) that adequately represent populations to which the results are applied and directly assess effects on health outcomes. • Meta-analyses of such studies. Highly certain about the estimate of effect. Further research is unlikely to change confidence in the estimate of effect.	High
• RCTs with minor limitations‡ affecting confidence in, or applicability of, the results. • Well-designed, well-executed nonrandomized controlled studies§ and well-designed, well-executed observational studies¶. • Meta-analyses of such studies. Moderately certain about the estimate of effect. Further research may have an impact on confidence in the estimate of effect and may change the estimate.	Moderate
• RCTs with major limitations. • Nonrandomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results. • Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports). • Physiological studies in humans. • Meta-analyses of such studies. Low certainty about the estimate of effect. Further research is likely to have an impact on confidence in the estimate of effect and is likely to change the estimate.	Low

*In some cases, other evidence, such as large all-or-none case series (e.g., jumping from airplanes or tall structures), can represent high- or moderate-quality evidence. In such cases, the rationale for the evidence rating exception should be explained by the Work Group and clearly justified.

†"Well-designed, well-executed" refers to studies that directly address the question; use adequate randomization, blinding, and allocation concealment; are adequately powered; use intention-to-treat analyses; and have high follow-up rates.

‡Limitations include concerns with the design and execution of a study that result in decreased confidence in the true estimate of the effect. Examples of such limitations include but are not limited to: inadequate randomization, lack of blinding of study participants or outcome assessors, inadequate power, outcomes of interest that are not prespecified for the primary outcomes, low follow-up rates, and findings based on subgroup analyses. Whether the limitations are considered minor or major is based on the number and severity of flaws in design or execution. Rules for determining whether the limitations are considered minor or major and how they will affect rating of the individual studies will be developed collaboratively with the methodology team.

§Nonrandomized controlled studies refer to intervention studies where assignment to intervention and comparison groups is not random (e.g., quasi-experimental study design).

¶Observational studies include prospective and retrospective cohort, case-control, and cross-sectional studies.

Applying Classification of Recommendations and Level of Evidence

	Size of Treatment Effect				
	CLASS I *Benefit >>> Risk*	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed*	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional*	CLASS III *No Benefit* or Class III *Harm*	
				Procedure/Test	**Treatment**

		Procedure/Treatment SHOULD be performed/ administered	IT IS REASONABLE to perform procedure/administer treatment	Procedure/Treatment MAY BE CONSIDERED	COR III: No Benefit	Not helpful	No proven benefit
					COR III: Harm	Excess cost without benefit or harmful	Harmful to patients
Estimate of Certainty (Precision) of Treatment Effect	LEVEL A Multiple populations evaluated* Data derived frommultiple randomized clinical trials or meta-analyses	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence frommultiple randomized trials or meta-analyses	• Recommendation in favor oftreatment or procedure being useful/effective • Some conflicting evidence frommultiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence frommultiple randomized trials or meta-analyses	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Sufficient evidence frommultiple randomized trials or meta-analyses		
	LEVEL B Limited populations evaluated* Data derived froma single randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is useful/effective • Evidence from single randomized trial or nonrandomized studies	• Recommendation in favor oftreatment or procedure being useful/effective • Some conflicting evidence fromsingle randomized trial or nonrandomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence fromsingle randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Evidence fromsingle randomized trial or nonrandomized studies		
	LEVEL C Very limited populations evaluated* Only consensus opinion ofexperts, case studies, or standard ofcare	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard ofcare	• Recommendation in favor oftreatment or procedure being useful/effective • Only diverging expert opinion, case studies, or standard ofcare	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard ofcare	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Only expert opinion, case studies, or standard ofcare		

Size of Treatment Effect *registry data would be helpful*

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative-effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Clinical Algorithm(s)

An algorithm titled "Implementation of Risk Assessment Work Group Recommendations" is provided in the original guideline document.

Scope

Disease/Condition(s)

Atherosclerotic cardiovascular disease (ASCVD)

Guideline Category

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Cardiology

Endocrinology

Family Practice

Internal Medicine

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To develop or recommend an approach to quantitative risk assessment that could be used to guide care
- To use systematic review methodology to pose and address a small number of questions judged to be critical to refining and adopting risk assessment in clinical practice

Target Population

Adult population without clinical signs or symptoms of atherosclerotic cardiovascular disease (ASCVD)

Note: These recommendations do not apply to those with clinically manifest ASCVD, who require secondary prevention approaches, or to highly-selected patient subgroups, such as those with symptoms suggestive of cardiovascular disease (CVD), who require diagnostic strategies rather than risk assessment. Furthermore, these recommendations were not developed for use in specific subgroups of asymptomatic individuals at unusually high risk, such as those with genetically determined extreme values of traditional risk factors (e.g., patients with familial hypercholesterolemia).

Interventions and Practices Considered

1. Assessment of 10-year risk of a first hard atherosclerotic cardiovascular disease (ASCVD) event, including use of race- and sex-specific Pooled Cohort Equations to predict 10-year risk of a first hard ASCVD event
2. Use of newer risk markers
    - After quantitative risk assessment if treatment decision uncertain (family history, high-sensitivity C-reactive protein [hs-CRP], coronary artery calcium [CAC] score, or ankle-brachial index [ABI])
    - Routine measurement of carotid intima-media thickness (CIMT) (not recommended)
    - Assessment of apolipoprotein B (ApoB), chronic kidney disease (CKD), albuminuria, and cardiorespiratory fitness (no recommendation for or against)
3. Long-term risk assessment

Major Outcomes Considered

- Cardiovascular disease (CVD) mortality
- Fatal or nonfatal myocardial infarction
- Fatal or nonfatal stroke
- Hospitalization for or death from arrhythmia
- Hospitalization for or death from congestive heart failure (CHF)
- Composite CVD outcomes

- Risk for a first CVD event

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Infrastructure, Search Strategy Development, and Validation

The literature search was performed using an integrated suite of search engines that explored a central repository of citations and full text journal articles. The central repository, search engines, search results, and Web-based modules for literature screening and data abstraction were integrated within a technology platform called the Virtual Collaborative Workspace (VCW). The VCW was custom-developed for the National Heart, Lung and Blood Institute (NHLBI) guidelines initiative.

The central repository consisted of 1.9 million citations and 71,000 full text articles related to cardiovascular disease risk reduction. Citations were acquired from PubMed, EMBASE, CINAHL, Cochrane, PsycINFO, Wilson Science, and Biological Abstracts databases. Literature searches were conducted using a collection of search engines, including TeraText, Content Analyst, Collexis, and Lucene. The first three engines were used for executing search strategies, and Lucene was used to correlate the search with literature screening results.

For every critical question, literature search and screening were conducted according to the understanding of the question and the inclusion and exclusion (I/E) criteria that provided specific characteristics of studies relevant to the question. Criteria were framed in the PICOTSS format, and the question and PICOTSS components were translated into a search strategy involving Boolean and conceptual queries.

A Boolean query encodes both inclusion and exclusion rules. It grants access to the maximum quantity of citations, which are then analyzed by text analytics tools and ranked to produce a selection for literature screening. Two independent reviewers conducted this screening in the VCW's Web-based module. Boolean queries select citations by matching words in titles and abstracts, as well as medical subject headings (MeSH) and subheadings. The number of citations resulting from Boolean queries has ranged from a few hundred to several thousand, depending on the question. The text analytics tools suite included:

- A natural language processing module for automated extraction of data elements to support the application of I/E criteria. Data elements that were frequently extracted and used were study size and intervention follow up period.
- Content Analyst for automatically expanding vocabulary of queries, conceptual retrieval, and conceptual clustering. The conceptual query engine employed in Content Analyst leverages word frequency features and co-occurrence in similar contexts to index, select, and rank results. The indexing uses the singular value decomposition (SVD) algebraic method.
- TeraText for ranking search results and executing operations on literature collections.

Search strategy development was intertwined with the results of literature screening, which provided feedback on search quality and context. Screened literature was categorized into two subsets: relevant or not relevant to the question. Next, results were analyzed to determine the characteristics of relevant versus not relevant citations. Additional keywords and MeSH terms were used to expand or contract the scope of the query as driven by characteristics of relevant citations. If the revised search strategy produced citations that did not undergo the screening process, then a new batch of citations was added for review. The search strategy refinement/literature review cycle was repeated until all citations covered by the most recent Boolean query had been screened.

Each search strategy was developed and implemented in the VCW. The search strategy was reviewed by the methodologist and panel members, and was available for viewing and printing at any time by panel members and staff collaborating on the systematic review. It was available for execution and for supplying literature updates until the literature search and screening cut-off date.

Search strategies for a sample of questions were validated by an independent methodology team. This validation process involved developing and executing a separate search strategy and screening a random sample of citations against I/E criteria. These results were compared to the search and screening results developed by the systematic review team. As an additional validation method, studies identified in systematic reviews and meta-analyses were cross-checked against a critical question's Include List to ensure completeness of the search strategy.

Process for Literature Review

Using results of the search strategy, criteria were applied to screen literature for inclusion or exclusion in the evidence base for the critical question. I/E criteria address the parameters in the PICOTSS framework and determine what types of studies are eligible and appropriate to answer the critical question. Additional criteria, such as sample size restrictions, were included by the panel to fit the context of the critical question.

Pilot Literature Screening Mode

In the pilot literature screening mode, two reviewers independently screened the first 50 titles/abstracts in the search strategy results by applying I/E criteria. Reviewers voted to include the publication for full text review or voted to exclude it. Reviewers compared their results to ensure that I/E criteria were applied consistently. Discrepancies in votes were discussed, and clarification on criteria was sought from the panel where appropriate. For example, if criteria were not specific enough to be clearly applied to include or exclude a citation, guidance was sought to more explicitly word criteria.

During this phase, reviewers provided feedback to the literature search team about the relevance of search strategy results; this feedback was used to further refine and optimize the search.

Phase 1: Title and Abstract Screening Phase

After completing the pilot mode phase, two reviewers independently screened search results at the title and abstract levels by applying I/E criteria. Reviewers voted to include or exclude the publication for full text review.

Titles and abstracts that one or both reviewers voted to include advanced to phase 2, full text screening. Titles and abstracts where both reviewers voted to exclude were excluded and not reviewed further. These citations are maintained in the VCW and marked as "excluded at title/abstract phase."

Phase 2: Full Text Screening Phase

Titles and abstracts that at least one reviewer voted to include were reviewed at the full text level in phase 2. In this phase, two reviewers independently applied I/E criteria to the full text article and voted for: include, exclude, or undecided. The reviewer had to specify the rationale for exclusion (e.g., population, intervention) in this phase.

Articles that both reviewers voted to include were moved to the Include List. Articles that both reviewers voted to exclude were moved to the Exclude List. These citations were maintained in the VCW and identified as "excluded at the full article phase," and the rationale for exclusion was noted. Any article with discrepant votes (i.e., one include and one undecided, one include and one exclude) advanced to phase 3.

Phase 3: Resolution and Consultation Phase

In this phase, reviewers discussed their vote for include, exclude, or undecided and cited the relevant criteria for their decision. The two reviewers attempted to achieve consensus through collaborative discussion. If a decision was not reached between the two reviewers, they asked the methodologist for advice. If a decision was not reached after consultation with the methodologist, the panel was consulted. However, the methodologist had the final decision. The final disposition of the article (include or exclude) was recorded in the VCW along with comments from the adjudication process.

Similarly to search strategies, which are posted and available for viewing on the VCW, all citations screened for a critical question are maintained in the VCW with their reviewer voting status and all collected comments.

Risk Assessment Question 1 Search Strategy Results

Risk Assessment Question 1 was initially intended to be a de novo systematic review of original studies plus systematic reviews and meta-analyses. In 2011, the question was de-scoped and restricted to systematic reviews/meta-analyses (SR/MA) only. The initial search included the following bibliographic databases. On April 27, 2011, a supplemental search from PubMed was executed that sought exclusively SR/MA.

- PubMed from January 1998 to December 2009, later extended to April 2011
- CINAHL from January 1998 to July 2008
- EMBASE from January 1998 to July 2008
- PsycINFO from January 1998 to July 2008
- EBM (Evidence-Based Medicine) Cochrane Libraries from January 1998 to July 2008
- Biological Abstracts from January 2004 to July 2008
- Wilson Social Sciences Abstracts from January 1998 to July 2008

Duplicate citations that arose from the same citation being found in more than one database were removed from the central repository before screening.

Additional supplemental literature searches were conducted to find publications up to September 19, 2013. The initial search strategy was re-done and run in seven databases with small modifications in the different databases resulting in 678 additional references. PubMed, EMBASE, CINAHL, Cochrane Database of Systematic Reviews, were searched from 2008 to September 2013. Biosis (Biological Abstracts), PsycINFO, Wilson Social Sciences Abstracts were searched from July 2008 to September 2013. Although a search had been run previously in PubMed up to April 2011, PubMed was searched again from 2008 to September 2013. Searches were limited primarily to systematic reviews and meta-analyses.

Risk Assessment Question 2 Search Strategy Results

The following databases were searched for prospective or retrospective cohort studies, randomized controlled trials (RCTs), and systematic reviews to answer Question 2:

- PubMed from January 1998 to December 2009
- CINAHL from January 1998 to July 2008
- EMBASE from January 1998 to July 2008
- PsycINFO from January 1998 to July 2008
- EBM (Evidence-Based Medicine) Cochrane Libraries from January 1998 to July 2008
- Biological Abstracts from January 2004 to July 2008
- Wilson Social Sciences Abstracts from January 1998 to July 2008

Duplicate citations that arose from the same citation being found in more than one database were removed from the central repository before screening.

Number of Source Documents

Risk Assessment Question 1 Search Strategy Results

The search produced 2,803 citations; this number includes the search for original studies and systematic reviews/meta-analyses (SR/MA) sought from the initial search plus results from the supplemental search that was restricted to SR/MA. The titles and abstracts of these 2,803 publications were screened against the inclusion/exclusion (I/E) criteria independently by two reviewers, which resulted in the retrieval of 770 full-text papers. These papers were independently screened by two reviewers, and 762 of these publications were excluded on one or more of the I/E criteria. The most common reason for exclusion was that the intervention did not meet specified criteria. Thus, a total of 8 SR/MA were eligible for inclusion in the Question 1 evidence base.

Risk Assessment Question 2 Search Strategy Results

The search produced 2,338 citations. An additional 10 citations published after December 2009 were retrieved from PubMed for review. The titles and abstracts of these 2,348 publications were screened against the I/E criteria independently by two reviewers, which resulted in the retrieval of 348 full-text papers. These papers were independently screened by two reviewers and 338 of these publications were excluded on one or more of the I/E criteria. The most common reason for exclusion was that the intervention did not meet specified criteria. Thus, 10 publications were eligible for inclusion in the Question 2 Evidence Base. None of the 10 citations published after December 2009 that were reviewed met the inclusion criteria.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Applying Classification of Recommendations and Level of Evidence

	Size of Treatment Effect			

		CLASS I	CLASS IIa	CLASS IIb	CLASS III *No Benefit* or Class III *Harm*		
		Benefit >>> Risk Procedure/Treatment SHOULD be performed/ administered	*Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure/administer treatment	*Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment MAY BE CONSIDERED		**Procedure/Test**	**Treatment**
					COR III: No Benefit	Not helpful	No proven benefit
					COR III: Harm	Excess cost without benefit or harmful	Harmful to patients
Estimate of Certainty (Precision) of Treatment Effect	LEVEL A Multiple populations evaluated* Data derived frommultiple randomized clinical trials or meta-analyses	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence frommultiple randomized trials or meta-analyses	• Recommendation in favor oftreatment or procedure being useful/effective • Some conflicting evidence frommultiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence frommultiple randomized trials or meta-analyses	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Sufficient evidence frommultiple randomized trials or meta-analyses		
	LEVEL B Limited populations evaluated* Data derived froma single randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is useful/effective • Evidence from single randomized trial or nonrandomized studies	• Recommendation in favor oftreatment or procedure being useful/effective • Some conflicting evidence fromsingle randomized trial or nonrandomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence fromsingle randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Evidence fromsingle randomized trial or nonrandomized studies		
	LEVEL C Very limited populations evaluated* Only consensus opinion ofexperts, case studies, or standard ofcare	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard ofcare	• Recommendation in favor oftreatment or procedure being useful/effective • Only diverging expert opinion, case studies, or standard ofcare	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard ofcare	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Only expert opinion, case studies, or standard ofcare		

Size of Treatment Effect

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative-effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

National Heart, Lung and Blood Institute (NHLBI) Quality Rating of the Strength of Evidence

Type of Evidence	**Quality Rating***
• Well-designed, well-executed† randomized controlled trials (RCTs) that adequately represent populations to which the results are applied and directly assess effects on health outcomes. • Meta-analyses of such studies. Highly certain about the estimate of effect. Further research is unlikely to change confidence in the estimate of effect.	High
• RCTs with minor limitations‡ affecting confidence in, or applicability of, the results. • Well-designed, well-executed nonrandomized controlled studies§ and well-designed, well-executed observational studies¶. • Meta-analyses of such studies. Moderately certain about the estimate of effect. Further research may have an impact on confidence in the estimate of effect and may change the estimate.	Moderate
• RCTs with major limitations. • Nonrandomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results. • Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports). • Physiological studies in humans. • Meta-analyses of such studies. Low certainty about the estimate of effect. Further research is likely to have an impact on confidence in the estimate of effect and is likely to change the estimate.	Low

*In some cases, other evidence, such as large all-or-none case series (e.g., jumping from airplanes or tall structures), can represent high- or moderate-quality evidence. In such cases, the rationale for the evidence rating exception should be explained by the Work Group and clearly justified.

†"Well-designed, well-executed" refers to studies that directly address the question; use adequate randomization, blinding, and allocation concealment; are adequately powered; use intention-to-treat analyses; and have high follow-up rates.

‡Limitations include concerns with the design and execution of a study that result in decreased confidence in the true estimate of the effect. Examples of such limitations include but are not limited to: inadequate randomization, lack of blinding of study participants or outcome assessors, inadequate power, outcomes of interest that are not prespecified for the primary outcomes, low follow-up rates, and findings based on subgroup analyses. Whether the limitations are considered minor or major is based on the number and severity of flaws in design or execution. Rules for determining whether the limitations are considered minor or major and how they will affect rating of the individual studies will be developed collaboratively with the methodology team.

§Nonrandomized controlled studies refer to intervention studies where assignment to intervention and comparison groups is not random (e.g., quasi-experimental study design).

¶Observational studies include prospective and retrospective cohort, case-control, and cross-sectional studies.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Directed by the National Heart, Lung and Blood Institute (NHLBI), with input from the expert panels and work groups, the contractor staff:

- Determined, by two independent raters, the quality of each included study. The methodology staff, with input from NHLBI, adapted study-rating instruments and trained study raters on the use of these instruments
- Abstracted relevant information from the included studies into an electronic database, and constructed and used templates with lists of data elements pertinent to the established inclusion/exclusion criteria to support abstraction
- Constructed detailed evidence tables, which organized the data from the abstraction database
- Analyzed the evidence tables and constructed summary tables, which display the evidence in a manageable format to answer specific parts of the Question

The expert panels and work groups:

- Used summary tables to develop evidence statements for each Question. The quality of evidence for each evidence statement was graded as high, moderate, or low based on scientific methodology, scientific strength, and consistency of results (see the "Rating Scheme for the Strength of the Evidence" field). Used the graded evidence statements to write clinical recommendations and graded the strength of each recommendation

The strength of the body of evidence represents the degree of certainty, based on the overall body of evidence, that an effect or association is correct. Appendix A of the full work group report supplement (see the "Availability of Companion Documents" field) describes how four domains of the body of evidence—risk for bias, consistency, directness, and precision—were used to grade the strength of evidence.

The full work group report supplement also contains background and additional material related to content, methodology, evidence synthesis, rationale, and references and is supported by the *NHLBI Systematic Evidence Review* (see the "Availability of Companion Documents" field). These documents also describe the process for the development of novel, comprehensive multivariable risk equations for the prediction of 10-year risk of development of atherosclerotic cardiovascular disease (ASCVD) in non-Hispanic African-American and non-Hispanic white men and women from 40 to 79 years of age. These equations were developed from several long-standing population-based cohort studies funded by the NHLBI. Ten-year risk was defined as the risk of developing a first ASCVD event, defined as nonfatal myocardial infarction or coronary heart disease (CHD) death or fatal or nonfatal stroke, over a 10-year period among people free from ASCVD at the beginning of the period.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American College of Cardiology (ACC) and the American Heart Association (AHA) have collaborated with the National Heart, Lung and Blood Institute (NHLBI) and stakeholder and professional organizations to develop clinical practice guidelines for assessment of cardiovascular

risk, lifestyle modifications to reduce cardiovascular risk, management of blood cholesterol in adults, and management of overweight and obesity in adults.

In 2008, the NHLBI initiated these guidelines by sponsoring rigorous systematic evidence reviews for each topic by expert panels convened to develop critical questions (CQs), interpret the evidence, and craft recommendations. In response to the 2011 report from the Institute of Medicine on the development of trustworthy clinical guidelines, the NHLBI Advisory Council recommended that the NHLBI focus specifically on reviewing the highest-quality evidence and partner with other organizations to develop recommendations. Accordingly, in June 2013 the NHLBI initiated collaboration with the ACC and AHA to work with other organizations to complete and publish the 4 guidelines noted above and make them available to the widest possible constituency. Recognizing that the Expert Work Group/Work Groups did not consider evidence beyond 2011 (except as specified in the methodology), the ACC, AHA, and collaborating societies plan to begin updating these guidelines starting in 2014.

The joint ACC/AHA Task Force on Practice Guidelines (Task Force) appointed a subcommittee to shepherd this transition, communicate the rationale and expectations to the writing panels and partnering organizations, and expeditiously publish the documents. The ACC/AHA and partner organizations recruited a limited number of expert reviewers for fiduciary examination of content, recognizing that each document had undergone extensive peer review by representatives of the NHLBI Advisory Council, key federal agencies, and scientific experts. Each writing panel responded to comments from these reviewers. Clarifications were incorporated where appropriate, but there were no substantive changes because the bulk of the content was undisputed.

Although the Task Force led the final development of these prevention guidelines, they differ from other ACC/AHA guidelines. First, as opposed to an extensive compendium of clinical information, these documents are significantly more limited in scope and focus on selected CQs on each topic, based on the highest-quality evidence available. Recommendations were derived from randomized trials, meta-analyses, and observational studies evaluated for quality and were not formulated when sufficient evidence was not available. Second, the text accompanying each recommendation is succinct, summarizing the evidence for each question. The Full Panel/Work Group Reports include more detailed information about the evidence statements that serve as the basis for recommendations. Third, the format of the recommendations differs from other ACC/AHA guidelines. Each recommendation has been mapped from the NHLBI grading format to the ACC/AHA Classification of Recommendation/Level of Evidence (COR/LOE) construct (see the "Rating Scheme for the Strength of the Evidence" field) and is expressed in both formats. Because of the inherent differences in grading systems and the clinical questions driving the recommendations, alignment between the NHLBI and ACC/AHA formats is in some cases imperfect. Explanations of these variations are noted in the recommendation tables, where applicable.

Organization of the Work Group

The Risk Assessment Work Group (Work Group) was composed of 11 members and 5 ex-officio members, including internists, cardiologists, endocrinologists, and experts in cardiovascular epidemiology, biostatistics, healthcare management and economics, and guideline development.

Charge to the Work Group

The Work Group was 1 of 3 work groups appointed by the NHLBI to develop its own recommendations and provide cross-cutting input to 3 Panels for updating guidelines on blood cholesterol, blood pressure (BP), and overweight/obesity. The Work Group was asked to examine the scientific evidence on risk assessment for initial atherosclerotic cardiovascular disease (ASCVD) events and to develop an approach for quantitative risk assessment that could be used in practice and used or adapted by the risk factor panels (blood cholesterol, hypertension, and obesity) in their guidelines and algorithms.

Specifically, the Work Group was charged with 2 tasks:

1. To develop or recommend an approach to quantitative risk assessment that could be used to guide care; and
2. To use systematic review methodology to pose and address a small number of questions judged to be critical to refining and adopting risk assessment in clinical practice.

Description of How Panels Developed and Prioritized Critical Questions

After panels were convened, members were invited to submit topic areas or questions for systematic review. Members were asked to identify topics of the greatest relevance and impact for the target audience of the guideline, which is primary care providers.

Proposed questions and topic areas were collected from panel members over a period of several months. The number of critical questions was scoped, and questions were prioritized based on clinical importance. After group discussion, panel members ranked priority critical questions through a combination of collaborative dialogue and voting.

With support from the methodologist and systematic review team, priority critical questions were formulated. Inclusion/exclusion (I/E) criteria were

defined and formatted using the PICOTSS framework. PICOTSS is a framework for a structured research question and includes the following components in the statement of the critical question or in the question's I/E criteria: P (person, population); I (intervention, exposure); C (comparator); O (outcome), T (timing), S (setting); (S study design).

I/E criteria define the parameters for the selection of literature for a particular critical question. They were developed with help from the methodologist and systematic review team to ensure that criteria were clear and precise and could be applied consistently across literature identified in the search.

The final critical questions and criteria were submitted to the literature search team for search strategy development.

The 2 critical questions (CQ) were:

CQ1: What is the evidence regarding reclassification or contribution to risk assessment when high-sensitivity C-reactive protein (hs-CRP), apolipoprotein B (ApoB), glomerular filtration rate (GFR), microalbuminuria, family history, cardiorespiratory fitness, ankle-brachial index (ABI), carotid intima-media thickness (CIMT), or coronary artery calcium (CAC) score are considered in addition to the variables that are in the traditional risk scores?

CQ2: Are models constructed to assess the long-term (≥15 years or lifetime) risk for a first cardiovascular disease (CVD) event in adults effective in assessing variation in long-term risk among adults at low and/or intermediate short-term risk, whether analyzed separately or combined?

CQ-Based Approach

The body of this report is organized by critical question. For each question, the Risk Assessment Work Group:

- Provides the rationale for its selection and describes the methods
- Summarizes the body of evidence and presents evidence statements that include a rating for quality; a narrative summary supports each evidence statement
- Accompanies recommendations and recommendation strength with a summary of how the recommendation derives from the evidence and discusses issues taken into consideration by the expert panel in formulating the recommendation

A detailed description of methods is provided in the appendixes. The appendixes present all tools used to develop the present systematic reviews, as well as documentation for search strategies and results from the search of the published literature.

Development of Evidence Statements, Recommendations, and Panel Voting

Using the summary tables (and evidence tables as needed), evidence statements were collaboratively written by expert panel members with input from methodology staff and oversight of the process by NHLBI staff. Evidence statements aimed to summarize key messages from the evidence that could be provided to primary care physicians and other stakeholders. In some cases, the evidence was too limited or inconclusive, so no evidence statement was developed, or a statement of insufficient evidence was made.

Once evidence statements were finalized, attention turned to recommendations. Recommendations were developed using a similar process to evidence statements. Voting could be open so that differing viewpoints could be identified easily and further discussion and revisions facilitated to address areas of disagreement (e.g., by crafting language or dividing an evidence statement into more than one statement). Voting could be by confidential ballot if the group chose. For both evidence statements and recommendations, a record of the vote count (for, against, recusal) was made without attribution. The ideal was 100 percent consensus, but a 2/3 majority was considered acceptable. For approval of a recommendation rated E (Expert Opinion) at least 75 percent of the expert panel members had to vote "yes."

Rating Scheme for the Strength of the Recommendations

Note: Each recommendation has been mapped from the National Heart, Lung and Blood Institute (NHLBI) grading format below to the American College of Cardiology/American Heart Association (ACC/AHA) Classification of Recommendation/Level of Evidence (COR/LOE) construct (see the "Rating Scheme for the Strength of the Evidence" field) and is expressed in both formats.

NHLBI Grading of the Strength of Recommendations

Grade	Strength of Recommendation*
A	Strong recommendation

Grade	Strength of Recommendation*
A	There is high certainty based on evidence that the net benefit† is substantial.
B	Moderate recommendation There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.
C	Weak recommendation There is at least moderate certainty based on evidence that there is a small net benefit.
D	Recommendation against There is at least moderate certainty based on evidence that there is no net benefit or that risks/harms outweigh benefits.
E	Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group recommends.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the Work Group thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area.
N	No recommendation for or against ("There is insufficient evidence or evidence is unclear or conflicting.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Work Group thought no recommendation should be made. Further research is recommended in this area.

*In most cases, the strength of the recommendation should be closely aligned with the quality of the evidence; however, under some circumstances, there may be valid reasons for making recommendations that are not closely aligned with the quality of the evidence (e.g., strong recommendation when the evidence quality is moderate, such as smoking cessation to reduce cardiovascular disease [CVD] risk or ordering an electrocardiogram [ECG] as part of the initial diagnostic work-up for a patient presenting with possible myocardial infarction [MI]). Those situations should be limited and the rationale explained clearly by the Work Group.

†Net benefit is defined as benefits minus risks/harms of the service/intervention.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

A formal peer review process, which included 12 expert reviewers and representatives of federal agencies, was initially completed under the auspices of the National Heart, Lung and Blood Institute (NHLBI). This document was also reviewed by 3 expert reviewers nominated by the American College of Cardiology (ACC) and the American Heart Association (AHA) when the management of the guideline transitioned to the ACC/AHA.

This document was approved for publication by the governing bodies of the ACC and AHA and endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipid Association, Preventive Cardiovascular Nurses Association, and WomenHeart: The National Coalition for Women with Heart Disease.

This document was approved by the American College of Cardiology Board of Trustees and the American Heart Association Science Advisory and Coordinating Committee in November 2013. The Academy of Nutrition and Dietetics affirms the value of this guideline.

Evidence Supporting the Recommendations

References Supporting the Recommendations

References Supporting the Recommendations

Ankle Brachial Index Collaboration, Fowkes FG, Murray GD, Butcher I, Heald CL, Lee RJ, Chambless LE, Folsom AR, Hirsch AT, Dramaix M, deBacker G, Wautrecht JC, Kornitzer M, Newman AB, Cushman M, Sutton-Tyrrell K, Fowkes FG, Lee AJ, Price JF, d'Agostino RB, Murabito JM, Norman PE, Jamrozik K, Curb JD, Masaki KH, Rodriguez BL, Dekker JM, Bouter LM, Heine RJ, Nijpels G, Stehouwer CD, Ferrucci L, McDermott MM, Stoffers HE, Hooi JD, Knottnerus JA, Ogren M, Hedblad B, Witteman JC, Breteler MM, Hunink MG, Hofman A, Criqui MH, Langer RD, Fronek A, Hiatt WR, Hamman R, Resnick HE, Guralnik J, McDermott MM. Ankle brachial index combined with Framingham Risk Score to predict cardiovascular events and mortality: a meta-analysis. JAMA. 2008 Jul 9;300(2):197-208. [48 references] PubMed

Buckley DI, Fu R, Freeman M, Rogers K, Helfand M. C-reactive protein as a risk factor for coronary heart disease: a systematic review and meta-analyses for the U.S. Preventive Services Task Force. Ann Intern Med. 2009 Oct 6;151(7):483-95. [98 references] PubMed

Dawber TR, Kannel WB, Lyell LP. An approach to longitudinal studies in a community: the Framingham Study. Ann N Y Acad Sci. 1963 May 22;107:539-56. PubMed

Den Ruijter HM, Peters SA, Anderson TJ, Britton AR, Dekker JM, Eijkemans MJ, EngstrÃ¶m G, Evans GW, de Graaf J, Grobbee DE, Hedblad B, Hofman A, Holewijn S, Ikeda A, Kavousi M, Kitagawa K, Kitamura A, Koffijberg H, Lonn EM, Lorenz MW, Mathiesen EB, Nijpels G, Okazaki S, OLeary DH, Polak JF, Price JF, Robertson C, Rembold CM, Rosvall M, Rundek T, Salonen JT, Sitzer M, Stehouwer CD, Witteman JC, Moons KG, Bots ML. Common carotid intima-media thickness measurements in cardiovascular risk prediction: a meta-analysis. JAMA. 2012 Aug 22;308(8):796-803. PubMed

Emerging Risk Factors Collaboration, Kaptoge S, Di Angelantonio E, Lowe G, Pepys MB, Thompson SG, Collins R, Danesh J. C-reactive protein concentration and risk of coronary heart disease, stroke, and mortality: an individual participant meta-analysis. Lancet. 2010 Jan 9;375(9709):132-40. PubMed

Empana JP, Tafflet M, Escolano S, Vergnaux AC, Bineau S, Ruidavets JB, Montaye M, Haas B, Czernichow S, Balkau B, Ducimetiere P. Predicting CHD risk in France: a pooled analysis of the D.E.S.I.R., Three City, PRIME, and SU.VI.MAX studies. Eur J Cardiovasc Prev Rehabil. 2011 Apr;18(2):175-85.

Fried LP, Borhani NO, Enright P, Furberg CD, Gardin JM, Kronmal RA, Kuller LH, Manolio TA, Mittelmark MB, Newman A. The Cardiovascular Health Study: design and rationale. Ann Epidemiol. 1991 Feb;1(3):263-76. PubMed

Friedman GD, Cutter GR, Donahue RP, Hughes GH, Hulley SB, Jacobs DR, Liu K, Savage PJ. CARDIA: study design, recruitment, and some characteristics of the examined subjects. J Clin Epidemiol. 1988;41(11):1105-16. PubMed

Helfand M, Buckley DI, Freeman M, Fu R, Rogers K, Fleming C, Humphrey LL. Emerging risk factors for coronary heart disease: a summary of systematic reviews conducted for the U.S. Preventive Services Task Force. Ann Intern Med. 2009 Oct 6;151(7):496-507. [212 references] PubMed

Kannel WB, Feinleib M, McNamara PM, Garrison RJ, Castelli WP. An investigation of coronary heart disease in families. The Framingham offspring study. Am J Epidemiol. 1979 Sep;110(3):281-90. PubMed

Karp I, Abrahamowicz M, Bartlett G, Pilote L. Updated risk factor values and the ability of the multivariable risk score to predict coronary heart disease. Am J Epidemiol. 2004 Oct 1;160(7):707-16. PubMed

Kashani M, Eliasson A, Vernalis M, Costa L, Terhaar M. Improving assessment of cardiovascular disease risk by using family history: an integrative literature review. J Cardiovasc Nurs. 2013 Nov-Dec;28(6):E18-27. PubMed

Lloyd-Jones DM, Leip EP, Larson MG, D'Agostino RB, Beiser A, Wilson PW, Wolf PA, Levy D. Prediction of lifetime risk for cardiovascular disease by risk factor burden at 50 years of age. Circulation. 2006 Feb 14;113(6):791-8. PubMed

Lloyd-Jones DM, Wilson PW, Larson MG, Beiser A, Leip EP, D'Agostino RB, Levy D. Framingham risk score and prediction of lifetime risk for coronary heart disease. Am J Cardiol. 2004 Jul 1;94(1):20-4. PubMed

Pencina MJ, D'Agostino RB, Larson MG, Massaro JM, Vasan RS. Predicting the 30-year risk of cardiovascular disease: the framingham heart study. Circulation. 2009 Jun 23;119(24):3078-84. PubMed

Peters SA, den Ruijter HM, Bots ML, Moons KG. Improvements in risk stratification for the occurrence of cardiovascular disease by imaging subclinical atherosclerosis: a systematic review. Heart. 2012 Feb;98(3):177-84. PubMed

Schnell-Inderst P, Schwarzer R, Gohler A, Grandi N, Grabein K, Stollenwerk B, Manne J, Klauss V, Siebert U, Wasem J. Prognostic value, clinical effectiveness, and cost-effectiveness of high-sensitivity C-reactive protein as a marker for major cardiac events in asymptomatic individuals: a health technology assessment report. Int J Technol Assess Health Care. 2010 Jan;26(1):30-9.

The Atherosclerosis Risk in Communities (ARIC) Study: design and objectives. The ARIC investigators. Am J Epidemiol. 1989 Apr;129(4):687-702. PubMed

U.S. Preventive Services Task Force. Screening for peripheral artery disease and cardiovascular disease risk assessment with the ankle-brachial index in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2013 Sep 3;159(5):342-8. [17 references] PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate assessment of cardiovascular risk

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

These guidelines are meant to define practices that meet the needs of patients in most circumstances and are not a replacement for clinical judgment. The ultimate decision about care of a particular patient must be made by the healthcare provider and patient in light of the circumstances presented by that patient. As a result, situations might arise in which deviations from these guidelines may be appropriate. These considerations notwithstanding, in caring for most patients, clinicians can employ the recommendations confidently to reduce the risks of atherosclerotic cardiovascular disease (ASCVD) events.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Resources

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Goff DC Jr, Lloyd-Jones DM, Bennett G, Coady S, D'Agostino RB Sr, Gibbons R, Greenland P, Lackland DT, Levy D, O'Donnell CJ, Robinson JG, Schwartz JS, Shero ST, Smith SC Jr, Sorlie P, Stone NJ, Wilson PW. 2013 ACC/AHA guideline on the assessment ofÂ cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2935-59. [66 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Jul 1

Guideline Developer(s)

American College of Cardiology Foundation - Medical Specialty Society

American Heart Association - Professional Association

Source(s) of Funding

Development of the systematic review (see the "Availability of Companion Documents" field) was funded by the United States Government.

Development of the guideline was funded by the American College of Cardiology and the American Heart Association.

Guideline Committee

Risk Assessment Work Group

American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Subcommittee on Prevention Guidelines

Composition of Group That Authored the Guideline

Expert Work Group Members: David C. Goff, Jr, MD, PhD, FACP, FAHA (*Co-Chair*); Donald M. Lloyd-Jones, MD, SCM, FACC, FAHA (*Co-Chair*); Glen Bennett, MPH*; Sean Coady, MS*; Ralph B. D'Agostino, Sr, PhD, FAHA; Raymond Gibbons, MD, FACC, FAHA; Philip Greenland, MD, FACC, FAHA; Daniel T. Lackland, DrPH, FAHA; Daniel Levy, MD*; Christopher J. O'Donnell, MD, MPH*; Jennifer G. Robinson, MD, MPH, FAHA; J. Sanford Schwartz, MD; Susan T. Shero, MS, RN*; Sidney C. Smith, Jr, MD, FACC, FAHA; Paul Sorlie, PHD*; Neil J. Stone, MD, FACC, FAHA; Peter W. F. Wilson, MD, FAHA

*Ex-Officio Members

Methodology Members: Harmon S. Jordan, ScD; Lev Nevo, MD; Janusz Wnek, PhD

ACC/AHA Task Force Members: Jeffrey L. Anderson, MD, FACC, FAHA (*Chair*); Jonathan L. Halperin, MD, FACC, FAHA (*Chair-Elect*); Nancy M. Albert, PhD, CCNS, CCRN, FAHA; Biykem Bozkurt, MD, PhD, FACC, FAHA; Ralph G. Brindis, MD, MPH, MACC; Lesley H. Curtis, PhD, FAHA; David DeMets, PhD; Judith S. Hochman, MD, FACC, FAHA; Richard J. Kovacs, MD, FACC, FAHA; E. Magnus Ohman, MD, FACC; Susan J. Pressler, PhD, RN, FAAN, FAHA; Frank W. Sellke, MD, FACC, FAHA; Win-Kuang Shen, MD, FACC, FAHA

Subcommittee on Prevention Guidelines: Sidney C. Smith, Jr, MD, FACC, FAHA (*Chair*); Gordon F. Tomaselli, MD, FACC, FAHA (*Co-Chair*)

Financial Disclosures/Conflicts of Interest

In consultation with National Heart, Lung and Blood Institute (NHLBI), the policies adopted by the writing panels to manage relationships of authors with industry and other entities (RWI) are outlined in the methods section of each panel report. These policies were in effect when this effort began in 2008 and throughout the writing process and voting on recommendations, until the process was transferred to the American College of Cardiology/American Heart Association (ACC/AHA) in 2013. In the interest of transparency, the ACC/AHA requested that panel authors resubmit RWI disclosures as of July 2013. Relationships relevant to this guideline are disclosed in Appendices 1 and 2 in the original guideline document.

Expert panel members having relationships with industry or other possible conflicts of interest were allowed to participate in discussions leading up

to voting as long as they declared their relationships, but they recused themselves from voting on any issue relating to their RWI or potential COI.

Guideline Endorser(s)

American Association of Cardiovascular and Pulmonary Rehabilitation - Medical Specialty Society

American Society for Preventive Cardiology - Medical Specialty Society

American Society of Hypertension - Disease Specific Society

Association of Black Cardiologists - Medical Specialty Society

National Lipid Association - Professional Association

Preventive Cardiovascular Nurses Association - Medical Specialty Society

WomenHeart: The National Coalition for Women with Heart Disease - Nonprofit Organization

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Journal of the American College of Cardiology (ACC) Web site and from the Circulation Web site.

Print copies: Available from the ACC, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 (US only).

Availability of Companion Documents

The following are available:

- Risk Assessment Work Group. Assessing cardiovascular risk. Systematic evidence review from the Risk Assessment Work Group. Bethesda (MD): National Heart, Lung and Blood Institute (NHLBI); 2013. 139 p. Electronic copies: Available from the National Heart, Lung and Blood Institute (NHLBI) Web site.
- 2013 report on the assessment of cardiovascular risk: full work group report supplement. 2013. 184 p. Electronic copies: Available from the Journal of the American College of Cardiology Web site.
- 10 points to remember. Available from the American College of Cardiology (ACC) Web site. Also available as a video from the ACC Web site.
- 2013 ACC/AHA guideline on the assessment of cardiovascular risk. Slide set. 2013. 27 p. Electronic copies: Available from the ACC Web site.
- 2013 prevention guideline case vignettes. Available from the ACC Web site.
- Methodology manual and policies from the ACCF/AHA Task Force on Practice Guidelines. 2010 Jun. 88 p. American College of Cardiology Foundation and American Heart Association, Inc. Electronic copies: Available from the ACC Web site.

A pocket guideline is available from the Guideline Central Web site. The 2013 Prevention Guidelines ASCVD Risk Estimator is available as a mobile app or in a web version from the ACC Web site.

Print copies: Available from the ACC, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 (US only).

Patient Resources

The following is available:

- Guideline on the assessment of cardiovascular risk. Patient resource. Available from the American College of Cardiology Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on October 3, 2014. The information was verified by the guideline developer on January 23, 2015.

Copyright Statement

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.